

## **REMARKS**

### **I. Nationalization**

This application represents the U.S. national stage under 35 U.S.C. § 371 of International Patent Application PCT/AU2003/000972, filed July 31, 2003, which claims priority to Russian Application Serial No. 2002120366, filed August 01, 2002.

Although the text of the International Application was transmitted to the U.S. receiving office from the International Bureau, as a precaution under 35 U.S.C. § 371(c)(2), an additional copy is enclosed herewith in the form of the published PCT Application WO 2004/013108.

An amendment is made to page 1 of the specification to insert the claims for priority and an amendment is made at page 5 of the specification to correct a typographical error. A single paragraph abstract is also provided as a separate page by amendment. These amendments to the specification comply with the revisions to 37 C.F.R. § 1.121.

### **II. National Stage Claims**

After according a U.S. filing date, and **before** calculating the filing fee, entry of the foregoing claim amendments is respectfully requested.

The original, unamended claims in the PCT application, as published in WO 2004/013108, form the basis for the amendments introduced herein.

As the claims in the PCT application were drafted with multiple dependencies and certain second medical use claims, Applicants have revised the claims to better accord with U.S. practice and to place the application in form for U.S. examination. The changes to the claims are being made solely to achieve these objectives, thereby also reducing the filing fee. The submission of new claims does not represent abandonment of any of the subject matter of the claims in the PCT application. Indeed, the present claims are fully supported by the claims in the PCT application,

as well as by the specification and claims of the PCT and priority application, and the new claims do not in any way constitute new matter.

### **III. Status of the Claims**

The PCT application was filed with claims 1-50. PCT examination indicated each of claims 1-50 to have unity of invention, which should be noted upon entry into the U.S. national stage. After the Written Opinion, claim 26 was amended on June 28, 2004 to correct a typographical error and insert an omitted space. Thus, at the time of the International Preliminary Examination Report (IPER), claim 26 in the PCT application had been amended.

According to the revisions to 37 C.F.R. § 1.121, entry into the U.S. national stage should account for the changes to the claims since the designation of the U.S. Therefore, prior to entry into the national stage, claims 1-50 were pending. Presently, claims 2, 3, 6, 7, 11-26, 30, 31, 35, 37-41, 43 and 44 have been amended without prejudice or disclaimer, to better accord with U.S. practice. Claims 45-50 have been canceled without prejudice or disclaimer, as not complying with U.S. requirements. No claims have been added.

Claims 1-44 are therefore in the case. According to the revisions to 37 C.F.R. § 1.121(c), a copy of the pending claims is provided in the amendment section.

### **IV. Support for the Claims**

The revisions to the claims are being made to better accord with U.S. practice and to reduce the filing fee. The present claims are fully supported by the claims in the PCT application, in addition to the specification.

Claim 2 has been revised to better accord with U.S. practice.

Claim 3 has been revised to depend only from claim 1.

Claim 6 has been revised to depend only from claim 4.

Claims 7 and 11 have each been revised to depend only from claim 3.

Claim 12 has been revised to depend only from claim 11.

Claims 13 and 14 have each been revised to depend only from claim 3.

Claims 15, 16 and 17 have each been revised to depend only from claim 1.

Each of claims 18-25 have been revised to better accord with U.S. practice.

Claim 26 has been revised to depend only from claim 1.

Claims 30, 31, 35, 37 and 38 have each been revised to depend only from claim 27.

Claim 39 has been revised to be a dependent claim and to depend from claim 27.

Claims 40 and 41 have each been revised to be dependent claims and to depend from claim 39.

Claim 43 has been revised to provide an additional independent claim based upon claims 1 and 2.

Finally, claim 44 has been revised to provide an additional composition claim, as originally represented in claim 39.

It will therefore be understood that no new matter is encompassed by any of the amended claims.

## **V. Patentability**

The International Preliminary Examination Report (IPER) (copy enclosed) issued for the PCT application established unity of invention for all PCT claims. The present claims, which represent the claims in the PCT application, but revised to better accord with U.S. practice, are therefore drawn to a unified invention for the purposes of examination in the U.S.

Importantly, the IPER also indicated both novelty and inventive step for each of PCT claims 1-50. PCT claims 1-50 correspond to the present U.S. claims, except the second medical use claims have been canceled as being drawn to non-statutory subject matter. The present U.S. claims are thus directed to subject matter determined to be novel and inventive during PCT examination, as set forth in the IPER. This is compelling evidence that the U.S. claims also define a novel and non-obvious invention. In light of the positive IPER, Applicants therefore respectfully request an early indication of allowance for the present application.

#### **VI. Fees and Formalities**

The national filing fee and claim fees are included herewith. The fees have been calculated according to the new fee schedule and **after** the present changes to remove the multiple dependencies in the claims. Any omitted fees should be deducted from Williams, Morgan & Amerson, P.C. Deposit Account No. 50-0786/4050.003100. Applicants are believed to be entitled to pay small entity fees. However, as a precaution, large entity fees are being paid and a refund will be requested within two months of filing.

As further precautions for the U.S. application, additional versions of the formal drawings are presently enclosed. The executed formal documents and any procedural requirements deemed necessary by the Office will be completed in due course. Should the Office have any questions, a telephone call to the undersigned Applicant's representative is earnestly solicited.

Respectfully submitted,  
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